

CLAIMS

1. A granule formulation comprising 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and a
5 freely or very water-soluble binder, wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns.
2. A formulation according to claim 1 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine is in the form of a fumarate salt.
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3. A formulation according to either claim 1 or claim 2 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].
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4. A formulation according to claim 3 wherein the binder is maltodextrin.
5. A formulation according to any one of claims 1 to 4 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.
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6. A formulation according to any one of claims 1 to 5 which further comprises a sweetener.
7. A granule formulation consisting of 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzol[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof, a freely
25 or very water-soluble binder, and a sweetener wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns.
- 30 8. A formulation according to claim 7 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzol[b,f][1,4]thiazepine is in the form of a fumarate salt.

9. A formulation according to any one of claims 1 to 8 wherein the moisture level in the granules is between 1.5 and 15%.
10. A formulation according to claim 9 wherein the moisture level in the granules is
5 between 4 and 8%.
11. A process for preparing a formulation as defined in claim 1 which process comprises
i) fluidising one or more components on a bed of air in a fluid bed;
ii) adding to the fluid bed, water optionally containing one or more components;
10 iii) drying.
12. A process according to claim 11 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzol[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and the freely or very water-soluble binder are fluidised on a bed of air.
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13. A granule formulation as defined in claim 1 for use in a method of therapeutic treatment of a patient in need thereof.
14. Use of a granule formulation as defined in claim 1 in the manufacture of a medicament
20 for the treatment of diseases of the central nervous system, such as psychoses, in particular schizophrenia.
15. A method for treating diseases of the central nervous system, such as psychoses, in particular schizophrenia, which comprises administering an effective amount of a formulation
25 as defined in claim 1 to a patient in need thereof.
16. A kit comprising
i) a granule formulation as defined in any one of claims 1 to 10;
ii) an aqueous medium;
30 iii) optionally, instructions for use so that the granules can be dissolved or suspended in said aqueous medium for administration.

- 13 -

17. A sachet containing a granule formulation as defined in any one of claims 1 to 10.